PATENTS

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Robert J. D'Amato**	Art Unit: **1614**
Serial No.: **09/545,139**	Examiner: **Goldberg, J.**
Filed: **April 7, 2000**	
For: **Methods and Compositions for the Inhibition of Angiogenesis with EM-138**	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Prior to examination of the above-identified patent application, please enter the following amendments.

In The Written Description

Please substitute the paragraph on page 1, between lines 17-20, as follows:

This application is a divisional of Application serial No. 08/950,673, filed October 16, 1997, now U.S. Patent No. 6,071,948, which is a continuation-in-part of U.S. Patent Application Serial No. 08/025,046, filed March 1, 1993.

Please substitute the paragraph beginning page 2, line 31, and ending page 3, line 19, as follows:

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being sent by facsimile transmission to the Examiner Jerome Goldberg, to facsimile number 703-746-5148, on May 6, 2002.

Jeffery B. Arnold – Reg. No. 39,540

ATLIB02 78765.1

One example of a disease mediated by angiogenesis is ocular neovascular disease. This disease is characterized by invasion of new blood vessels into the structures of the eye such as the retina or cornea. It is the most common cause of blindness and is involved in approximately twenty eye diseases. In age-related macular degeneration, the associated visual problems are caused by an ingrowth of chorioidal capillaries through defects in Bruch's membrane with proliferation of fibrovascular tissue beneath the retinal pigment epithelium. Angiogenic damage is also associated with diabetic retinopathy, retinopathy of prematurity, corneal graft rejection, neovascular glaucoma and retrolental fibroplasia. Other diseases associated with corneal neovascularization include, but are not limited to, epidemic keratoconjunctivitis, Vitamin A deficiency, contact lens overwear, atopic keratitis, superior limbic keratitis, pterygium keratitis sicca, sjogrens, acne rosacea, phylectenulosis, syphilis, *Mycobacteria* infections, lipid degeneration, chemical burns, bacterial ulcers, fungal ulcers, *Herpes simplex* infections, *Herpes zoster* infections, protozoan infections, Kaposi sarcoma, Mooren ulcer, Terrien's marginal degeneration, mariginal keratolysis, rheumatoid arthritis, systemic lupus, polyarteritis, trauma, Wegeners sarcoidosis, Scleritis, Steven's Johnson disease, pemphigoid, radial keratotomy, and corneal graph rejection.

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Please substitute the paragraph beginning page 23, line 24, and ending on page 24, line 4, as follows:

Diseases associated with corneal neovascularization that can be treated according to the present invention include, but are not limited to, diabetic retinopathy, retinopathy of prematurity, corneal graft rejection, neovascular glaucoma and retrolental fibroplasia, epidemic keratoconjunctivitis, Vitamin A deficiency, contact lens overwear, atopic keratitis, superior limbic keratitis, pterygium keratitis sicca, sjogrens, acne rosacea, phylectenulosis, syphilis, *Mycobacteria* infections, lipid degeneration, chemical burns, bacterial ulcers, fungal ulcers, *Herpes simplex* infections, *Herpes zoster* infections, protozoan infections, Kaposi sarcoma, Mooren

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ulcer, Terrien's marginal degeneration, mariginal keratolysis, trauma, rheumatoid arthritis, systemic lupus, polyarteritis, Wegeners sarcoidosis, Scleritis, Steven's Johnson disease, pemphigoid, radial keratotomy, and corneal graph rejection.

Please delete the paragraphs beginning on page 24, line 22, through page 26, line 9.

Please substitute the paragraph beginning on page 26, lines 10-19 as follows:

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Another disease which can be treated according to the present invention is rheumatoid arthritis. It is believed that the blood vessels in the synovial lining of the joints undergo angiogenesis. In addition to forming new vascular networks, the endothelial cells release factors and reactive oxygen species that lead to pannus growth and cartilage destruction. The factors involved in angiogenesis may actively contribute to, and help maintain, the chronically inflamed state of rheumatoid arthritis.

VERSION WITH MARKINGS TO SHOW CHANGES MADE UNDER 37 C.F.R. §1.121(c)(1)(ii)

Please amend the written description by deleting the bracketed word(s) and inserting the underlined word(s) as indicated.

In the Written Description

Please amend the paragraph on page 1, between lines 17-20, as follows:

This application is a divisional of Application serial No. 08/950,673, filed October 16, 1997, now U.S. Patent No. 6,071,948, which is a continuation-in-part of U.S. Patent Application Serial No. 08/025,046, filed March 1, 1993.

Please amend the paragraph beginning page 2, line 31, and ending page 3, line 19, as follows:

One example of a disease mediated by angiogenesis is ocular neovascular disease. This disease is characterized by invasion of new blood vessels into the structures of the eye such as the retina or cornea. It is the most common cause of blindness and is involved in approximately twenty eye diseases. In age-related macular degeneration, the associated visual problems are caused by an ingrowth of chorioidal capillaries through defects in Bruch's membrane with proliferation of fibrovascular tissue beneath the retinal pigment epithelium. Angiogenic damage is also associated with diabetic retinopathy, retinopathy of prematurity, corneal graft rejection, neovascular glaucoma and retrolental fibroplasia. Other diseases associated with corneal neovascularization include, but are not limited to, epidemic keratoconjunctivitis, Vitamin A deficiency, contact lens overwear, atopic keratitis, superior limbic keratitis, pterygium keratitis sicca, sjogrens, acne rosacea, phylectenulosis, syphilis, *Mycobacteria* infections, lipid degeneration, chemical burns, bacterial ulcers, fungal ulcers, *Herpes simplex* infections, *Herpes zoster* infections, protozoan infections, Kaposi sarcoma, Mooren ulcer, Terrien's marginal degeneration, mariginal keratolysis, rheumatoid arthritis, systemic lupus, polyarteritis,

trauma, Wegeners sarcoidosis, Scleritis, Steven's Johnson disease, [periphigoid] pemphigoid, radial keratotomy, and corneal graph rejection.

Please amend the paragraph beginning page 23, line 24, and ending on page 24, line 4, as follows:

Diseases associated with corneal neovascularization that can be treated according to the present invention include, but are not limited to, diabetic retinopathy, retinopathy of prematurity, corneal graft rejection, neovascular glaucoma and retrolental fibroplasia, epidemic keratoconjunctivitis, Vitamin A deficiency, contact lens overwear, atopic keratitis, superior limbic keratitis, pterygium keratitis sicca, sjogrens, acne rosacea, phylectenulosis, syphilis, *Mycobacteria* infections, lipid degeneration, chemical burns, bacterial ulcers, fungal ulcers, *Herpes simplex* infections, *Herpes zoster* infections, protozoan infections, Kaposi sarcoma, Mooren ulcer, Terrien's marginal degeneration, mariginal keratolysis, trauma, rheumatoid arthritis, systemic lupus, polyarteritis, Wegeners sarcoidosis, Scleritis, Steven's Johnson disease, [periphigoid] pemphigoid, radial keratotomy, and corneal graph rejection.

Please delete the paragraphs beginning page 24, line 22, through page 26, line 9.

Please amend the paragraph beginning page 26, line 10, and ending page 26, line 19, as follows:

Another disease which can be treated according to the present invention is rheumatoid arthritis. [Rheumatoid arthritis is a chronic inflammatory disease characterized by nonspecific inflammation of the peripheral joints.] It is believed that the blood vessels in the synovial lining of the joints undergo angiogenesis. In addition to forming new vascular networks, the endothelial cells release factors and reactive oxygen species that lead to pannus growth and cartilage destruction. The

factors involved in angiogenesis may actively contribute to, and help maintain, the chronically inflamed state of rheumatoid arthritis.

REMARKS

Applicant respectfully requests consideration and allowance of the above-identified application in view of the foregoing amendments and the following remarks.

Status of the Claims

Claims pending in the above-identified application are Claims 1, 3-9, 12, 14, 23-102. The claims are not amended.

Amendments to the Written Description

Upon a review of the above identified application, it was discovered that certain sections of the specification as filed were not consistent with the text of the parent application, U.S. Patent Application Serial No. 08/950,673, now U.S. Patent No. 6,071,948, as filed. In particular, the following sections were changed: Title, Cross-Reference to Related Application, Claims, and Abstract. Pursuant to 37 C.F.R. §§ 1.53(b) and 1.78(a)(2) and in accordance with M.P.E.P. §201.06(c), "an applicant may file a substitute specification [in a continuation or divisional application], ... so long as it does not result in the introduction of new matter." Applicant respectfully asserts that no new matter was introduced into the specification of the above-identified application by the changes to Title, Cross-Reference to Related Application, Claims, and Abstract.

It was also discovered that the paragraphs between page 24, line 22, and page 26, line 9, directed to chronic inflammatory diseases and a sentence on page 24, lines 11-13, directed to rheumatoid arthritis were inserted into the written description. However, the insertion of this text was inadvertent and unintentional, as evidenced by the Declaration of Kimberly J. Prior, attached hereto and made a part hereof as Exhibit "A". In order to bring the text of the written description into consistency with the written description of the parent application, Applicant has

deleted the aforementioned paragraphs and sentence. No new matter has been added by these amendments.

The paragraph on page 1, between lines 17-20, has been amended to reflect that the parent application has issued into a patent. The paragraph beginning page 2, line 31, and ending page 3, line 19, and the paragraph beginning page 23, line 24, and ending on page 24, line 4, have been amended to correct typographical errors. No new matter has been added by these amendments.

CONCLUSION

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes any informalities remain in the application that may be corrected by Examiner's amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney is earnestly solicited.

Respectfully submitted,

By: Jeffery B. Arnold
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Docket No. 05213-0650 (43170 – 219681)

Exhibit A

PATENTS

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re Application of: Docket No. **05213-0650 (43170-219681)**

Robert J. D'Amato

Serial No. **09/545,139**

Filed: **April 7, 2000**

For: **METHODS AND COMPOSITIONS FOR THE INHIBITION OF ANGIOGENESIS WITH EM-138**

Assistant Commissioner for Patents
Washington, D.C. 20231
Sir:

Transmitted herewith is a paper in the above-identified application.

☒ Preliminary Amendment.
☒ Exhibit A – Declaration of Kimberly J. Prior.

CERTIFICATE OF FACSIMILE

I hereby certify that this correspondence is being sent by facsimile transmission to the Examiner Jerome Goldberg, to facsimile number 703-746-5148, on May 6, 2002.

Signature

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1272
REFERENCE NO

43170/219681 (05213-0650)
CLIENT/MATTER NO.

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COMMENTS

The facsimile confirmation of the Patent Office imprinted hereon will acknowledge receipt of:

Applicant:	D'Amato
Title:	Methods and Compositions for the Inhibition of Angiogenesis with EM-138
Serial No./Docket No.:	09/545,139 05213-0650 (43170-219681)
Filing Date	April 7, 2000

PAPERS SUBMITTED:

1. Amendment Transmittal (1pp)
2. Preliminary Amendment (8pp)
3. Declaration of Kimberly J. Prior (2pp)

Date: May 6, 2002
By: Jeffery B. Arnold Reg. No. 39,540

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7/16/02